Heritage Information Systems, Inc.

Clinical Edit Criteria Proposal

SmartPA

Drug/Drug Class: 5-HT_1 Agonist (Triptan) Therapy

Prepared for: Missouri Medicaid
Prepared by: Heritage Information Systems, Inc.

☒ **New Criteria** ☐ **Revision of Existing Criteria**

Executive Summary

Purpose: Reduce drug costs by limiting the amount of triptans dispensed per prescription based on the maximum recommended dose per month of each agent.

Why was this Issue Selected: For the previous calendar year, (August 2001 – July 2002), Missouri Medicaid paid $4.4 million for triptans.

Program-specific information:

Drug	Claims	Expense
• Triptans	*30,093*	*$4,430,404*

Setting & Population: ≥ 18years of age

Type of Criteria: ☐ **Increased risk of ADE** ☐ **Non-Preferred Agent**
☒ **Appropriate Indications** ☐

Data Sources: ☒ **Only administrative databases** ☐ **Databases + Prescriber-supplied**

Purpose of Clinical Edit Criteria

Under the Omnibus Budget Reconciliation Act of 1993, Congress intended Prior Authorization or Prior Approval (PA) programs to control utilization of products that have very narrow indications or high abuse potential. While prescription expenditures are increasing at double-digit rates, payors are also evaluating ways to control these costs by influencing prescriber behavior and guide appropriate medication usage. Clinical Edit criteria, which is different from prior authorization or prior approval programs, assist in the achievement of qualitative and economic goals related to health care resource utilization without placing the entire utilization of a drug in a PA status. Screening the use of certain medications on the basis of clinical appropriateness can reduce costs by requiring evidence of appropriate indications for use, and where appropriate, encourage the use of less expensive agents within a drug class. Clinical Edit criteria can also reduce the risk for adverse events associated with medications by identifying patients at increased risk due to diseases or medical conditions, or those in need of dosing modifications.

Why Has This Clinical Issue Been Selected For Review?

Migraine headache is a chronic, debilitating condition that tends to afflict young, productive, otherwise healthy people. Migraines interfere with the activities of daily living, they decrease physical activity and appetite, and they increase fatigue and sensitivity to light and sound. Migraine frequency varies from as few as one to more than 10 attacks per month. They can be very debilitating, resulting in days lost from work and school. This costs our society at least $5 billion in lost productivity and 270 lost workdays for every 1000 workers each year.[1]

The triptans are the newest agents on the market indicated to abort acute migraine attacks and cluster headache (sumatriptan injection only). These agents offer selective pharmacology, established efficacy, a moderate side effect profile, and a well-established safety record. The disadvantages of these agents are their restrictions for use in the presence of cardiovascular disease and high cost.[2]

Safety and efficacy of treating more than four migraines per month has not been established. Overutilization of triptans can result in increased adverse drug effects and may lead to rebound or worsening of headaches.[3] Preventive therapy is generally recommended for patients experiencing three or more migraines per month, particularly if their migraines cause substantial disability and are not adequately relieved using acute migraine therapies.[3] Preventive therapy may help improve responsiveness to treatment of acute attacks. In order to prevent overutilization of triptans, the quantity of triptan dispensed per prescription will be limited to the maximum recommended doses for treating four migraine attacks per month as recommended by the manufacturers. The call center will review the use of preventive therapy with the prescriber. In addition, patients with specific co-morbidities and concomitant medications that present risks for an adverse event or drug-drug interaction will not receive authorization for triptan therapy at the point of sale. These patients will need further evaluation at the call center.

Approval Criteria

- **Drug class for review: 5-HT$_1$ agonists (**"Triptans")
- **Age range:** ≥ 18 years of age

Documented Diagnosis of Migraine

- **ICD-9 code category 346 in the last 2 years {346.0 – 346.9}**

A triptan prescription will be approved if the quantity per prescription does not exceed the maximum amount needed to treat 4 migraines per month at the maximum daily dose per product labeling (**see appendix**).

Denial Criteria

Requests for triptan therapy will be denied in the absence of approval criteria and under the following conditions:

- Ischemic heart disease
- Peripheral vascular syndromes
- Cerebrovascular disease
- Malignant hypertension
- Hemiplegic or basilar migraine
- Concurrent ergot therapy
- Concurrent MAOI therapy

Required Documentation

Laboratory results:	☐	Progress notes:	☐
MedWatch form:	☐		

References

1. APhA Special Report. Self-treatment of migraine and other types of headache. American Pharmaceutical Association.1998.
2. The US Headache Consortium: Evidence-based guidelines for migraine headache in the primary care setting: pharmacological management for prevention of migraine. American Academy of Neurology; 2000.
3. Goadsby JP, Lipton RB, Ferrari MD. Migraine – current understanding and treatment. N Engl J Med 2002; 346(4):257-270.
4. Facts and Comparisons, p 849-856, 2003.

APPENDIX

Maximum Monthly Quantity*

Product	Brand Name	Available dosages	Maximum Daily Dosage	Maximum Monthly Quantity*
Sumatriptan Injection	**Imitrex Inj**	6mg/0.5ml	12 mg (1ml)	4 mL 8x 0.5ml cartridges
Sumatriptan Tablets	**Imitrex**	25mg, 50mg, 100mg	200 mg	900 mg: 36 x 25 mg tabs 18 x 50mg tabs 9 x 100mg tabs
Sumatriptan Nasal	**Imitrex Nasal Spray**	5 and 20 mg unit of use	40 mg	160 mg: 32 x 5 mg 8 x 20 mg
Naratriptan	**Amerge**	1 mg, 2.5 mg	5mg	20 mg: 20 x 1 mg 8 x 2.5 mg
Zolmitriptan Tablets	**Zomig-Tablets, ZMT**	5 mg, 2.5 mg 2.5mg	10mg	30 mg: 12 x 2.5 mg tabs 6 x 5 mg tabs
Zolmitriptan Nasal spray	**Zomig Nasal Spray**	5mg	10mg	40mg
Rizatriptan benzoate	**Maxalt**	5mg, 10 mg	30mg	120 mg: 24 x 5 mg tabs 12 x 10 mg tabs
Rizatriptan benzoate-MLT	**Maxalt-MLT**			
Almotriptan	**Axert**	6.25mg, 12.5 mg	25 mg	100 mg: 16 x 6.25 mg tabs 8 x 12.5 mg tabs
Frovatriptan	**Frova**	2.5 mg	7.5 mg	12 x 2.5 mg tabs
Eletriptan	**Relpax**	20mg, 40mg	80mg	240mg: 12 x 20mg tabs 6 x 40mg tabs

* maximum monthly dose calculated at treating 4 episodes per month (excluding Zomig which was calculated at treating 3 episodes per month)